

Objective accommodation measurements in presbyopic eyes using an autorefractor and an aberrometer

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PURPOSE: To test the repeatability of the iTrace wavefront aberrometer (Tracey Technologies, Inc.) and the WR-5100K autorefractor (Grand Seiko Co., Ltd.) and to measure accommodation in young and phakic presbyopic subjects.

SETTING: University of Houston, College of Optometry, Houston, Texas, USA.

METHODS: This study comprised 30 young adults and 15 presbyopic subjects. Accommodation was stimulated with near charts presented at various distances. Measurements were repeated 3 times for each target distance with both instruments. For test–retest reliability, the entire protocol was repeated on 3 additional days in 3 presbyopic subjects as well as twice on the same day in the young adults.

RESULTS: The mean age was 25.5 years \pm 3.25 (SD) (range 21 to 31 years old) in the young adult group and 41.2 \pm 2.98 years (range 38 to 49 years) in the presbyopic group. Bland-Altman analysis of repeated measures of the young subjects had limits of agreements (LoA) of 1.58 diopters (D) or less for each instrument and when compared between instruments. Normalized mean stimulus response functions in the presbyopic group were similar for the 2 instruments. Bland-Altman analysis of the accommodation measurements between the 2 instruments showed a mean difference of 0.07 D and an LoA of 0.70 D. Repeated measures of 3 presbyopic subjects had a range of standard deviations from 0.07 to 0.51 D.

CONCLUSION: The accommodative responses measured with the 2 instruments were not significantly different, and testing showed both instruments to be suitable for objective measurement of accommodation in a phakic presbyopic population with low accommodative amplitudes.

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Accommodation is defined as an optical change in the power of the eye when viewing from far to near.^{1,2} Accommodation decreases with increasing age, ultimately resulting in an inability of the distance-corrected eye to focus at near in a condition called presbyopia.^{3,4} In humans, the progressive decline in accommodative amplitude begins in youth and culminates in a complete loss of accommodation.^{4–8} Although there are changes to most of the anatomical structures involved with accommodation with age (eg, altered ciliary body configuration, loss of capsule elasticity), the most significant change with age is increased stiffness of the lens.^{3,5,9–12}

There has been considerable interest in prospects for surgically restoring active and dynamic accommodation to the presbyopic eye with scleral expansion procedures or intraocular lenses (IOLs) designed to move with an accommodative effort to create a true change in the optical power of the eye for objects at near

distances.^{13–25} Although subjective clinical assessments suggest high levels of patient satisfaction and good visual performance,^{14,24–26} objectively measured accommodative performance with these procedures have been disappointing.^{16,27–29} Subjective accommodation testing, such as the routinely used clinical push-up test, is inappropriate for unequivocally demonstrating an accommodative optical change in the power of the eye.^{7,30} Subjective tests do not differentiate between passive depth of field due to small pupils and ocular aberrations and active accommodative power change in the eye. In addition, subjective tests significantly overestimate the true accommodative change when it is present.^{7,30–32} Although patient satisfaction and subjective performance are important, efforts to improve the performance of accommodation restoration procedures require objective measurements to understand the mechanisms of action. Furthermore, the

U.S. Food and Drug Administration has become increasingly vigilant regarding the labeling and claims for devices and procedures aimed at restoring accommodation. Thus, future clinical trials will likely require objective accommodation assessments if claims regarding accommodation restoration are to be made.

Clinical trials of accommodation restoration procedures require commercially available clinical instruments without the modifications that are sometimes used in laboratory studies.³³ An earlier study³² demonstrated the suitability of the commercially available WR-5100K autorefractor (Grand Seiko Co., Ltd.) for objective accommodation measurements. Similar objective accommodation testing could be performed with a clinical aberrometer if certain requirements could be met. Many autorefractors and aberrometers are specifically designed to prevent accommodation by having a fixed distant target or by fogging the eye before a measurement. To be suitable for accommodation testing, it must be possible to present a distant target (~ 0 diopter [D] accommodative demand) to measure the distance refraction and a near target at a variety of different accommodative demands as the eye is being measured. The instrument must have a sufficiently large dynamic range to measure the myopic change in the eye as the eye accommodates and should be capable of measuring through relatively small pupil diameters since the pupil constricts with an accommodative effort. The commercially available iTrace wavefront aberrometer (Tracey Technologies, Inc.) meets these requirements. In addition to measuring the change in spherical power of the eye, an aberrometer provides considerable additional information from the wavefront aberration measurement. The iTrace aberrometer uses a sequential ray-tracing method,³⁴⁻³⁶ which is different from the Hartmann-Shack principle aberrometers. The

sequential ray-tracing method may confer advantages for accommodation measurement, including a larger dynamic range. Also, the iTrace aberrometer may be less sensitive than Hartmann-Shack principle aberrometers to inaccuracies due to speckle noise because the iTrace aberrometer operates by detecting individual retinal spots and these retinal spots are substantially larger than the speckle noise.^{35,36} A study of an earlier version of the iTrace aberrometer found it to be reliable and robust for measuring refractive error.³⁷ It has also been shown that the iTrace aberrometer can be used to measure accommodation in young subjects using an internal target and positive lenses.^{38,39} In the current study, the iTrace aberrometer was compared with the WR-5100K autorefractor to test accommodation in older phakic subjects with low accommodative amplitudes using a real letter target in a clinical setting.

The present study was performed on phakic prepresbyopic subjects (ie, subjects with low but measurable accommodative amplitudes) for several reasons. If successful, first-generation accommodating IOLs are likely to restore only relatively low accommodative amplitudes and the largest segment of the patient population for accommodation restoration procedures will likely be prepresbyopes and early presbyopes. Therefore, it is necessary to develop accommodation testing protocols that are not unduly complex, long, or laborious; can be reliably administered; and can be shown to reliably measure accommodation in this population. If these protocols and instruments are found to be suitable in this population, additional testing can be performed to evaluate whether the instrumentation and protocols are suitable for testing patients with IOLs. Special considerations exist with IOLs, and these are not addressed by this study of phakic eyes. Intraocular lenses have flatter surface curvatures and a higher refractive index than the natural lens, and some new-generation IOLs have dual optics. These factors can result in bright and sometimes troublesome Purkinje image reflections off the IOL surfaces that may compromise instrument performance. Secondary posterior capsule opacification may also present challenges for these instruments. Therefore, it will ultimately be important to ensure the instruments can reliably measure eyes with such IOLs. However, a necessary first phase of such testing is to evaluate whether the instruments can reliably measure low accommodative amplitudes through small pupils. Phakic prepresbyopic subjects are therefore the ideal population for this testing.

The goal of this study was to compare the performance of the iTrace aberrometer and the WR-5100K autorefractor in their suitability for objectively measuring accommodation in a prepresbyopic population with low accommodative amplitudes. The

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accommodative responses measured with the WR-5100K autorefractor and the iTrace aberrometer and the repeatability of the measurements were compared over several days in the same subjects. In addition, the test-retest reliability of the instruments was compared in young subjects with higher accommodative amplitudes.

SUBJECTS AND METHODS

Subjects

Fifteen prepresbyopic subjects participated in the initial testing. Thirty young adult subjects participated in the repeatability testing of the 2 instruments. The subjects were recruited from the students, faculty, and staff of the University of Houston, College of Optometry, and their families. Informed consent was obtained in accordance with the Declaration of Helsinki and institutionally approved human subjects protocols. No subject had known ocular pathology or strabismus, and all were correctable to 20/20 in each eye with soft contact lenses. Exclusion criteria included astigmatism greater than 2.00 D and amblyopia (ie, best corrected visual acuity worse than 20/30). Three subjects had laser in situ keratomileusis in both eyes with no reported problems. Refractive errors, based on habitual prescriptions, ranged from +1.00 to -8.50 D of sphere and 0.00 to -1.75 D of astigmatism.

Subjects had eye examinations within 1 year of the study and reported their best-corrected distance refractive error (or their habitual refractive error). To avoid reflections from spectacle lenses and additional considerations of vertex distance or magnification/minification during the testing, all subjects were fitted with the best correction in soft contact lenses to fully correct refractive errors and astigmatism. Baseline distance refraction was the over-refraction through the soft contact lenses if correction was needed.

Instruments and Setup

WR-5100K Open-Field Autorefractor Testing with this instrument was similar to that described previously.³² Subjects viewed far or near targets through the 12.5 cm × 22 cm open-field beam splitter of the autorefractor. Although this instrument allows a binocular open field of view, for comparison with the iTrace aberrometer, subjects viewed the targets monocularly while the contralateral eye was blocked with the instrument occluder. The instrument software was set to a sensitivity of 0.01 D and a 0.0 mm vertex distance for measured refractions. The listed minimum pupil diameter that the WR-5100K autorefractor is able to measure through is 2.3 mm.

iTrace Aberrometer Subjects viewed far or near targets through the 2.5 cm diameter wide, 20 cm long open-field instrument housing. The iTrace aberrometer permits monocular viewing through the instrument and a monocular measurement that projects an infrared beam into the eye using laser ray-tracing technology and analyzes retinal spot patterns to determine the wavefront aberrations and refractive error. The instrument is sold with a removable Badal optometer that can be dioptrically adjusted to stimulate accommodation. For the experiments in this study, the optometer was removed to provide a testing situation comparable to that for the WR-5100K autorefractor. This allowed the subject to view through the instrument monocularly at real, far, or near

targets. A near-point rod holder on top of the instrument allowed a standard clinic near-point rod to be attached for viewing near targets. A real-distance target was viewed at 6 m through the instrument open-field housing. Sensitivity of the iTrace software was set at 0.12 D. The listed minimum pupil diameter the instrument can measure through is 2.5 mm. Testing showed the instrument was unable to autocapture measurements of pupil diameters smaller than 2.7 mm. Although the instrument can be set to take a manual measurement at a 2.0 mm pupil setting, this feature was not used in this study.

Target Luminance The iTrace monocular open field of view permits the far and near targets to be viewed monocularly through a beam splitter. This beam splitter is the last optical element in the measurement path and thus reduces the light to the eye from the targets. The distant target was a 30.55 cm high × 20.33 cm wide, self-illuminated Snellen chart with Sloan letters at 6 m (Precision Vision). The near target was a high-contrast miniaturized Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart printed in black on white paper. The near chart was suspended on a dioptrically calibrated near-point rod mounted on each instrument and was illuminated with a white light-emitting diode (LED) light source connected to a battery and a rheostat. Before testing, the near target luminance was measured through the iTrace with a photometer (Minolta LS-100, Minolta Camera Co., Ltd). Because the iTrace beam splitter blocks more visible light to the eye than the WR-5100K beam splitter, the target luminance (cd/m^2) measured through the iTrace aberrometer was maximized by increasing the illumination from the LED by adjusting the rheostat. Target luminance was first measured through the iTrace aberrometer; the same luminance was then set as measured through the WR-5100K open-field beam splitter. This maintained equal target luminance between the 2 instruments to avoid influencing the accommodative response.⁴⁰

Accommodation Testing Setup for Both Instruments

For the testing, the subject was seated at the instrument with his or her head stabilized in the instrument chin rest and forehead strap. Room illumination was dimmed to maintain large pupils and was measured to be 0.1 lux at the headrest of the instruments where the subject sat. For each far or near target presentation, 3 consecutive measurements were made with each instrument. Because all subjects wore their best correction in soft contact lenses, baseline distance refractions were close to plano. Therefore, large amounts of cylinder suggested off-axis measures or dryness from lack of blinking. If this occurred, the measurement was repeated.

Experimental Procedures

With the subject wearing his or her correction in soft contact lenses, best corrected distance visual acuity and near visual acuity were determined monocularly for each eye at 6 m and 40 cm, respectively. Two methods were then used to measure accommodation: (1) a subjective push-up test in free space and (2) an objective push-up test measured with the WR-5100K autorefractor and iTrace aberrometer.

Method 1: Subjective Accommodation in Free Space

Room illumination was turned on, and illumination from an overhead lamp was directed on the near chart. Distance-corrected subjects viewed the near letter chart (modified

ETDRS with Sloan letters by Lighthouse International) and focused on a letter 1 line larger than their best distance corrected near acuity, 1 eye at a time, with the other eye occluded. The chart was moved toward the subject slowly to allow the subject to accommodate until the subject reported first sustained blur. The reciprocal of the distance from the eye to the chart was recorded as the subjectively measured amplitude of accommodation. Three readings were taken from each eye. No subject required a starting distance greater than 40 cm or a near addition (add).

Method 2: Objective Accommodation with WR-5100K and iTrace

WR-5100K The subject sat with his or her head in the headrest of the instrument and viewed through the instrument beam splitter at the smallest line of letters on the distance letter chart that he or she could clearly read. The eye with the best distance acuity was used for testing, and the other eye was occluded. An initial test measurement was taken to ensure that the refraction measurements were on axis as off-axis measurements can affect accuracy.⁴¹ The subject was asked to observe the just perceptible, dim measurement ring light and to locate a letter on the letter chart that was at the center of the ring. If necessary, the chart was moved up or down to allow the subject to fixate on a letter that was close to his or her best acuity. This first measurement was not recorded. After the first measurement, the subject fixated on the selected letter for 3 additional measurements. The mean of these measurements was recorded as the subject's baseline refractive state.

To stimulate accommodation, the near target was moved closer to the subject in dioptric steps and the refraction measured at each step. The near target was mounted in front of the subject's line of sight on a near-point rod at 50.00, 40.00, 33.00, 28.50, 25.00, and 22.22 cm (corresponding to approximately 2.0, 2.5, 3.0, 3.5, 4.0, and 4.5 D, respectively). Stimulus amplitudes greater than 4.5 D were not used with the WR-5100K autorefractor. This was to maintain the same stimulus range used with the iTrace aberrometer, which was limited to 4.5 D due to the physical constraints of the instrument. An initial measurement was made, and the subject was again asked to find a fixation letter that was close to the center of the measurement ring light. Subsequently, 3 refraction measurements were taken for each near target distance.

iTrace The subject sat with his or her head in the headrest of the instrument. The instrument was aligned so the subject viewed through the instrument beam splitter and focused on the smallest line of letters on the distance letter chart that he or she could clearly read. The nonmeasured eye was occluded with an eye patch. To ensure on-axis refraction measurements, the subject was asked to fixate on a letter that was aligned with the center of the measurement light spot (visible during a measurement). The remaining procedures for measuring baseline refraction and accommodative responses for the near target distances were similar to those described for the WR-5100K autorefractor.

Occasional iTrace measurements presented as nonconcentric chaotic retinal spot patterns on the laptop monitor. These were recognized as questionable measurements. This was also expressed as an unusual refraction measurement, such as high astigmatism or hyperopic readings at near. This can occur as a result of an eye blink during the measurement

or drying of the cornea due to not blinking. If this occurred, the subject was reminded to maintain focus and fixation on the letter targets and to blink, after which another measurement was taken. If it was confirmed that the subject was focused and aligned and several repeat measurements gave the same result, the measurement was kept and examined later for aberrant or spurious spots in the wavefront. This entailed using iTrace software to scroll through the 256 retinal-spot profiles and ensure that the spot peaks were high enough and the software correctly located the horizontal and vertical peaks of each spot. This source of error, although infrequent, occurs when the retinal spots are dim and the spot profiles are relatively flat. When spurious spots were found, the spots were deleted using the iTrace software.

Repeat Measures and Order of Protocol

To test the repeatability of the instruments and protocols, 3 presbyopic subjects were measured 4 times through the same protocol on 4 separate days. On 1 visit, the order of the instruments was switched to make sure the subjects were not becoming fatigued after measurements with the first instrument.

In addition, to test the repeatability of the 2 instruments, 30 young adult subjects were run through a similar but abbreviated protocol twice each on the same day (3 measurements at 6 m, 2.0 D, and 4.0 D). The instrument used first was randomly selected. The measurements with the 2 instruments were compared. Younger subjects were used for this sub-study to ensure they had ample accommodation available.

Analysis

Because the WR-5100K autorefractor provides only sphere, cylinder, and axis, only the refraction measurement of the iTrace aberrometer was considered for the direct comparison between the 2 instruments. The wavefront data from the iTrace aberrometer were analyzed separately. Only the spherical component of the refraction measurements from both instruments was used, although both instruments measure sphere, cylinder, and axis. If the subject's pupil was larger than 4.5 mm, the iTrace aberrometer calculated the "autorefract" based on a 4.5 mm pupil. If the pupil was smaller than 4.5 mm, the iTrace aberrometer used the next smallest pupil size (3.0 or 2.0 mm). Accommodation was calculated for the objectively measured push-up method by subtracting the mean spherical refraction from the 3 measurements at each near distance from the mean baseline refraction of the 3 measurements recorded for the far distance.

Accommodation measurements by the WR-5100K autorefractor and iTrace aberrometer were compared using Bland-Altman analysis.⁴²

RESULTS

The mean age of the 8 female and 7 male presbyopic subjects who participated in the initial testing was 41.2 ± 2.98 years (38 to 49 years). The mean age of the 18 female and 13 male young adult subjects who participated in the repeatability testing was 25.5 ± 3.25 years (range 21 to 31 years).

In the presbyopic subjects, the mean accommodative amplitude for the 3 tests was $4.76 \text{ D} \pm 1.32$ (SD) (range 3.33 to 8.59 D) for the subjective push-up,

2.91 ± 1.01 D (range 0.59 to 4.45 D) for the WR-5100K, and 2.90 ± 0.99 D (range 0.71 to 4.04 D) for the iTrace. A comparison of the subjective push-up test with the WR-5100K objective test and iTrace objective test for each subject showed that the subjective test consistently overestimated the accommodative amplitude by between 0.54 D and 4.55 D (iTrace) or 1.04 D and 4.14 D (WR-5100K) (Figure 1, A). The mean subjectively measured push-up amplitude recorded for all subjects showed significantly greater accommodative amplitude with the 2 objective tests (iTrace: $P < 0.01$; WR-5100K: $P < 0.01$) (Figure 1, B). The mean objectively measured stimulus response functions for the 2 instruments showed no significant difference between the 2 instruments in the accommodative responses measured for each stimulus amplitude (F test = 0.552, $P = 0.591$) (Figure 2). Due to the different ages and, therefore the differing accommodative amplitudes, of the subjects, the data were normalized to 1 for the response recorded for the 4.5 D stimulus for both instruments.

Bland-Altman analysis of the refraction measured for all stimulus amplitudes from the 2 instruments showed a mean difference of -0.27 D and a 95% limit of agreement (LoA) of 0.95 D (Figure 3, A). Bland-Altman analysis of the accommodative responses to each stimulus amplitude from the 2 instruments showed a mean difference of 0.07 D and a 95% LoA of 0.70 D (Figure 3, B). This mean difference in accommodative response amplitude was below the resolution limits of the 2 instruments. The Bland-Altman graphs also showed no change in the magnitude of the difference between the 2 instruments with increasing accommodation.

Figure 4 shows the result of the repeatability of the accommodation tests in 3 subjects. Subject HH had a systematically greater lag of accommodation with the iTrace aberrometer (Figure 4, A). Subject AG had a marginally greater lag of accommodation with the WR-5100K autorefractor (Figure 4, B). Subject MW showed no difference between the 2 instruments (Figure 4, C). For all 3 subjects, the responses recorded with the 2 instruments over 4 days were similar, with standard deviations between the 4 repeated measures for each instrument ranging from 0.07 to 0.51 D.

Table 1 shows the results of test-retest reliability assessment performed on the 30 young subjects aged 21 to 31 years old. Between measurement 1 and 2, the WR-5100K autorefractor differed by 0.1 D and the iTrace aberrometer by 0.04 D, independent of the stimulus amplitude. The smallest difference between the 2 instruments was 0.02 D for the 2.0 D stimulus and the largest, 0.25 D for the 4.0 D stimulus.

Changes in higher-order aberrations (HOAs) were observed with the iTrace aberrometer, even through small undilated pupils. Total (unsigned) root-mean-

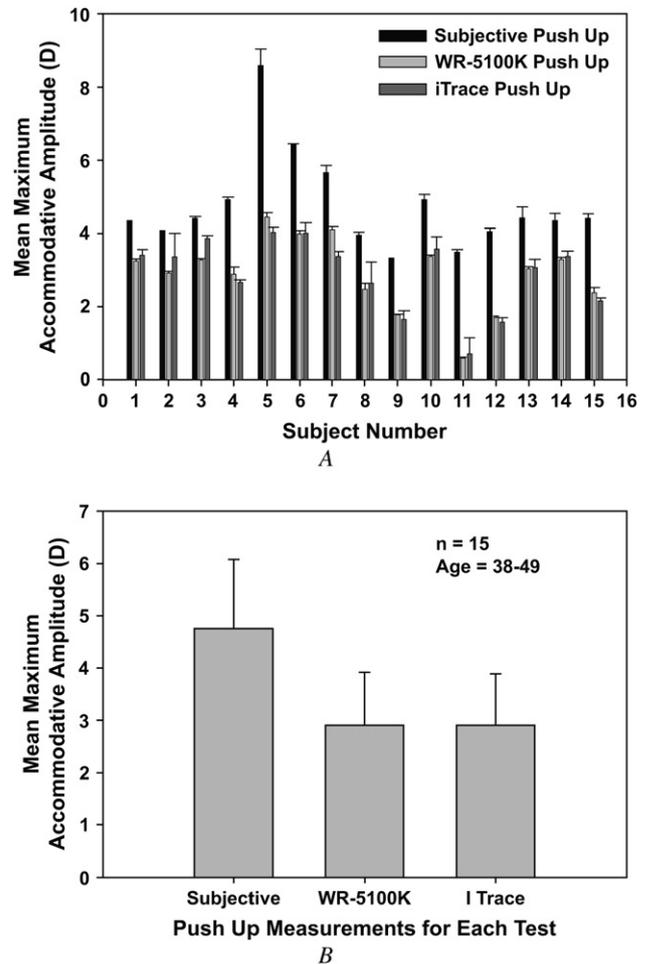


Figure 1. Individual (A) and mean (B) maximum accommodative amplitudes measured subjectively with the push-up test in free space and measured objectively for pushed-up near distances with the WR-5100K autorefractor and iTrace aberrometer. Error bars represent 1 standard error of the mean. Data are for all 15 prepresbyopic subjects.

square wavefront error compared with the spherical equivalent refraction recorded for all stimuli for the prepresbyopic and presbyopic subjects increased with more hyperopic resting refractions and as subjects accommodated (and refraction became more myopic) (graph not shown). Analysis of change in spherical aberration Z(4,0) as a function of accommodative response amplitudes showed that the change in spherical aberration increased linearly with increasing accommodative response (graph not shown) ($y = 0.031x + 0.049$; $r^2 = 0.093$; $P < 0.05$). This agrees with other studies of wavefront changes with accommodation.

Comparison of the refraction power map allows visualization of the power changes within the pupil. The iTrace software permits comparison of 2 wavefront measurements by showing the autorefractor measurements, near and far refraction power maps,

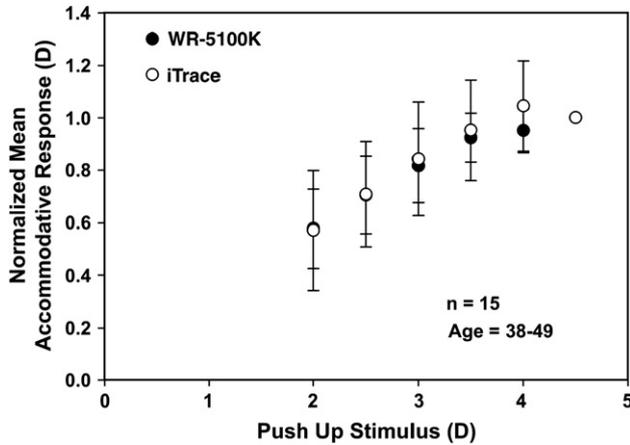


Figure 2. Stimulus response function for prepresbyopic subjects showing the mean accommodative responses to pushed-up near stimuli measured with the WR-5100K autorefractor and iTrace aberrometer. The data from each subject were normalized to the maximum response at 4.5 D.

and the difference power map. Comparison of the refraction power maps of 1 young subject (21 years old) between the distance refractions (baseline) and the response to a 4.00 D stimulus showed a clear change in dioptric power and a decrease in pupil diameter. The accommodated refraction power maps showed more oranges and reds, reflecting a myopic power, and the difference maps (distance minus near) showed more greens and blues, indicating a positive accommodative change in power (Figure 5).

The iTrace software can occasionally fail to correctly identify the centroid of a retinal spot. This can profoundly affect the refraction. This normally will occur when the retinal spot is dim with a flat profile or if there is a brighter peripheral region than centrally. In Figure 6, A and B, the 2 graphs to the right represent the horizontal and vertical luminance profiles (in yellow) of the retinal spot corresponding to beams currently selected by the software. As seen in Figure 6, A, the vertical luminance profile for the selected retinal spot shows an aberrant peak that is larger than the correct central peak. This failure to detect the correct centroid resulted in the retinal spot pattern appearing as a chaotic jumble (Figure 6, A). Figure 6, B, shows the corrected retinal spot pattern of this eye, showing the effect on the calculated autorefractor. With the 4 aberrant spots included, the autorefractor was $+4.00-4.87 \times 0.75$. This is clearly incorrect given that the subject's distance (baseline) refraction was $+1.12-0.37 \times 0.36$. With the aberrant spots manually deleted, the autorefractor was $-0.87-0.87 \times 53$. The effect of the aberrant spots was also apparent when comparing the uncorrected and corrected iTrace stimulus response functions of this subject with WR-5100K measurements (Figure 6, C and D). Once corrected, the iTrace stimulus

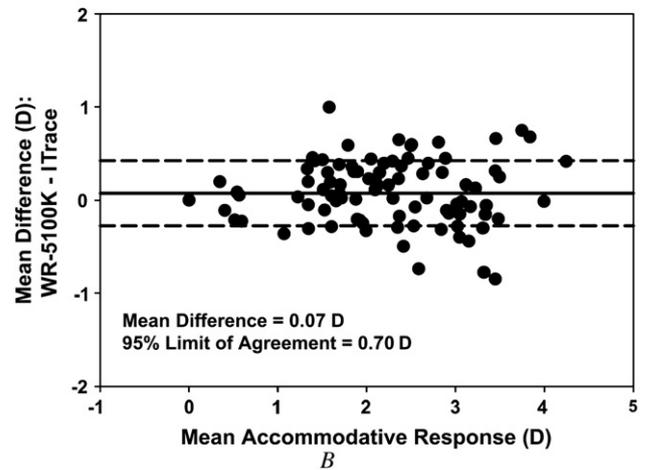
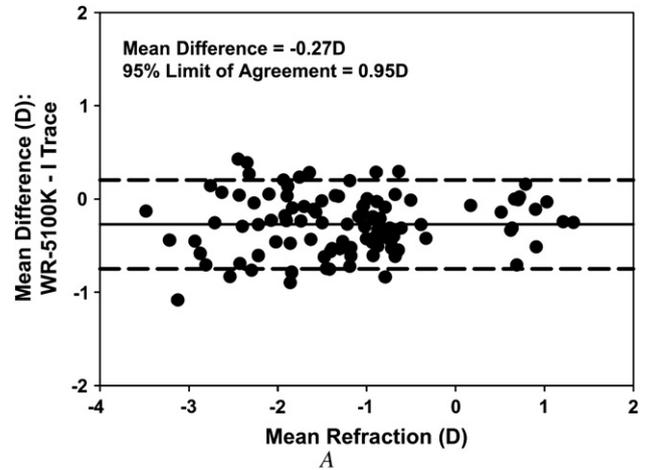


Figure 3. A: Mean versus difference Bland-Altman plot of the WR-5100K autorefractor and iTrace aberrometer for refraction measurements of each stimulus distance. B: Mean versus difference Bland-Altman plot of WR-5100K autorefractor and iTrace aberrometer for accommodative response of each stimulus distance.

response functions showed good agreement with the results of the WR-5100K autorefractor.

The autorefractor displayed by the iTrace aberrometer is the refraction calculated for the 4.5 mm pupil rounded to the nearest 0.12 D if this pupil diameter is available; otherwise, the iTrace aberrometer presents the autorefractor calculated from the next smallest pupil diameter. A Bland-Altman plot of the sphere from the "autorefractor" and the sphere from the refraction from the smallest available pupil diameter showed a mean difference of 0.00 D and a 95% LoA of 0.24 D (Figure 7).

DISCUSSION

In this study, a prepresbyopic population was evaluated using 2 instruments to determine the ability of the instruments to reliably measure low accommodative amplitudes. Variation in the amplitudes of this

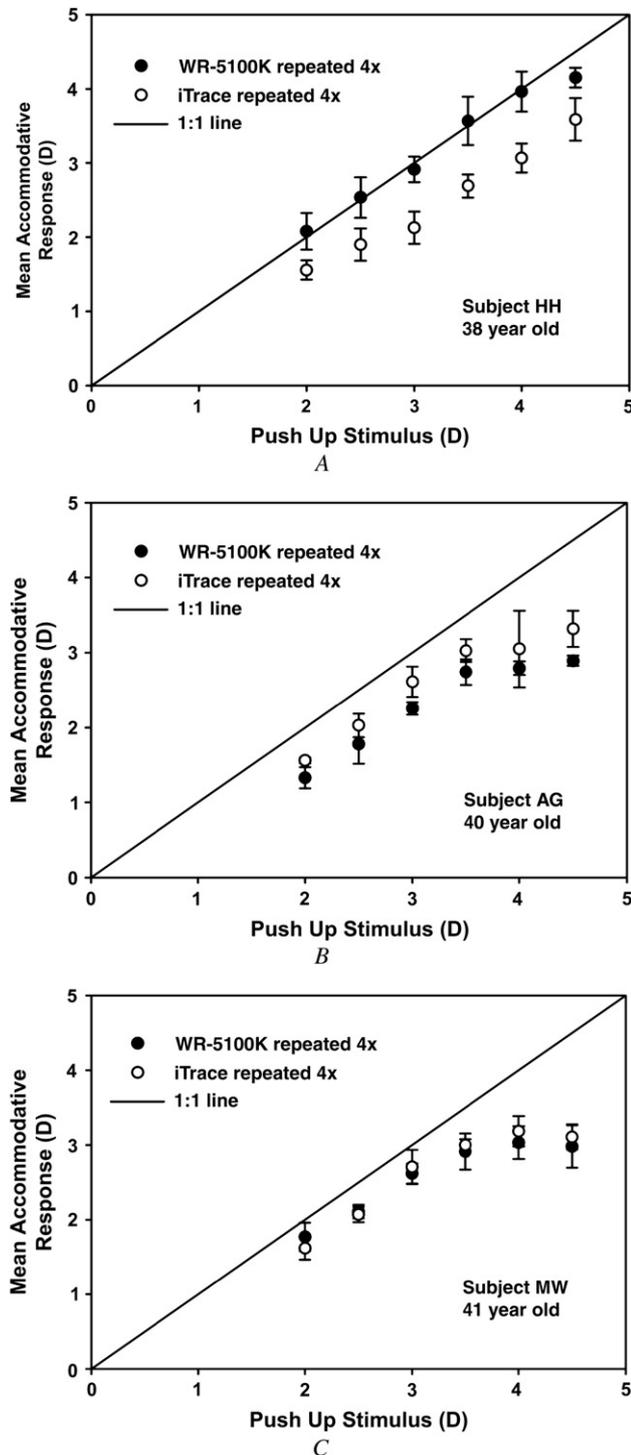


Figure 4. Stimulus response functions for 3 prepresbyopic subjects showing the mean accommodative responses to pushed-up near stimuli measured with the WR-5100K autorefractor and iTrace aberrometer 4 times over 4 different days. A: Subject HH (38 years old). B: Subject AG (40 years old). C: Subject MW (41 years old).

population of 38 to 49 year olds is expected (Figures 1, A, and 4, A to C). The normalized stimulus response graph (Figure 2) provided a stimulus response function

representative of this age group. This population has reduced, but still measurable, amplitudes of accommodation (approximately 3.00 D or less) (Figure 1, B). The lowest objectively measured accommodative amplitudes, 0.59 D (WR-5100K) and 0.71 D (iTrace), were measured in the 49-year-old subject and were still clinically significant. The 2 instruments were found to be suitable, equally accurate, and reliable in the measurement of low accommodative amplitudes in phakic eyes using the push-up method with real near targets. Measuring the dioptric change in power of the eye that occurs with low accommodative amplitudes is readily achievable in this population. Whether dioptric changes in power of this magnitude can be detected during accommodation in the pseudophakic eyes remains to be seen; however, there should not be an impediment in measuring small power changes as long as the instruments are able to measure pseudophakic eyes.

As a wavefront aberrometer, the iTrace provides additional useful information on the accommodative changes in the eye. As has been shown in humans and monkeys, the accommodative response of the young eye is accompanied by systematic changes in spherical aberration.^{43,44} However, large changes in spherical aberration with accommodation were not observed in the present study. In previous studies, the human eyes⁴³ were dilated with phenylephrine 2.5% and the monkeys were iridectomized.⁴⁴ The prepresbyopic subjects in the current study, with undilated natural pupil diameters, had considerably smaller pupils and would have had strong pupil constrictions with accommodation as well as lower accommodative amplitudes. Changes in spherical aberration within the natural pupils would therefore likely be small. Although large systematic changes in HOAs did not occur with accommodation in this population, the ability to observe such changes in wavefront aberrations and changes in refraction will be useful for studying any potential accommodation modality (eg, movement, bending, tilting, or flexure of an optic) in a pseudophakic population with “accommodating” IOLs.

As in previous studies of subjective and objective measures of accommodation,^{7,16,45} the subjective measurements of accommodation overestimated the objective measurements. For the 49-year-old subject, uncorrected distance refraction was measured to be -0.50 D with the WR-5100K autorefractor and -0.12 D with the iTrace aberrometer. This subject was able to read the 20/20 line of the near acuity chart at 40 cm and reported that there was no need to use a near add for reading. Although the objectively measured accommodative amplitude was 0.65 D (mean of WR-5100K and iTrace measurements), the subjectively measured accommodative amplitude was

Table 1. Bland-Altman analysis results comparing repeat number 1 and 2 and the 2 instruments for the 2 stimulus amplitudes (2.0 D and 4.0 D) for the repeatability testing.*

Test Condition	Near Stimulus (D)	Comparison	Mean Difference (D)	95% LoA
WR	2.0	1st - 2nd	0.115	1.196
WR	4.0	1st - 2nd	0.1106	1.507
IT	2.0	1st - 2nd	-0.0456	0.815
IT	4.0	1st - 2nd	-0.0428	0.868
1st repeat	2.0	IT - WR	0.0203	1.325
2nd repeat	2.0	IT - WR	0.1809	1.294
1st repeat	4.0	IT - WR	0.1006	1.575
2nd repeat	4.0	IT - WR	0.2539	1.512

IT = iTrace wavefront aberrometer; LoA = limit of agreement; WR = WR-5100K autorefractor

*WR or IT by itself represents a comparison of the instrument with itself (1st = first measurement versus 2nd = second measurement). IT-WR represents a comparison of the 2 instruments with each other.

3.49 D. Depth of focus and optimal aberrations, especially when accommodated for near with a small pupil diameter, are undoubtedly contributing factors to such a good uncorrected near acuity. Comparison of the mean maximum subjective accommodative amplitude in all subjects (4.76 D) and objective accommodative amplitude (2.90 D) showed a difference of almost 2.00 D (Figure 1, B). It is for this reason that objective measurements of accommodation are essential to unequivocally demonstrate an optical change in power of the eye to distinguish this from beneficial effects of pseudoaccommodation due to depth of field of the eye.

In this study, the iTrace aberrometer was compared with the WR-5100K autorefractor, which was validated for objective accommodation measurements in a previous study.³² Although the results of the 2 instruments were comparable and repeatable, there

are benefits and drawbacks to each. The iTrace aberrometer, when used in the standard autocapture mode, captures the refraction automatically whether the image of the eye is in focus (eg, a measurement can be taken inadvertently if the examiner or subject is not ready), which may result in the retinal spots being out of focus. This can be problematic if it causes aberrant spots because the subject was not fixating correctly or was blinking. The measurement can be repeated or the retinal spots examined and deleted to ensure there are no aberrant spots. That aberrant spots occasionally occur can significantly affect the data, and the need to examine the retinal spot patterns and delete them can be time consuming. After a measurement is taken, the data are not saved automatically and it is time consuming to manually save repeated measurements. Although brief, the infrared beam from the iTrace

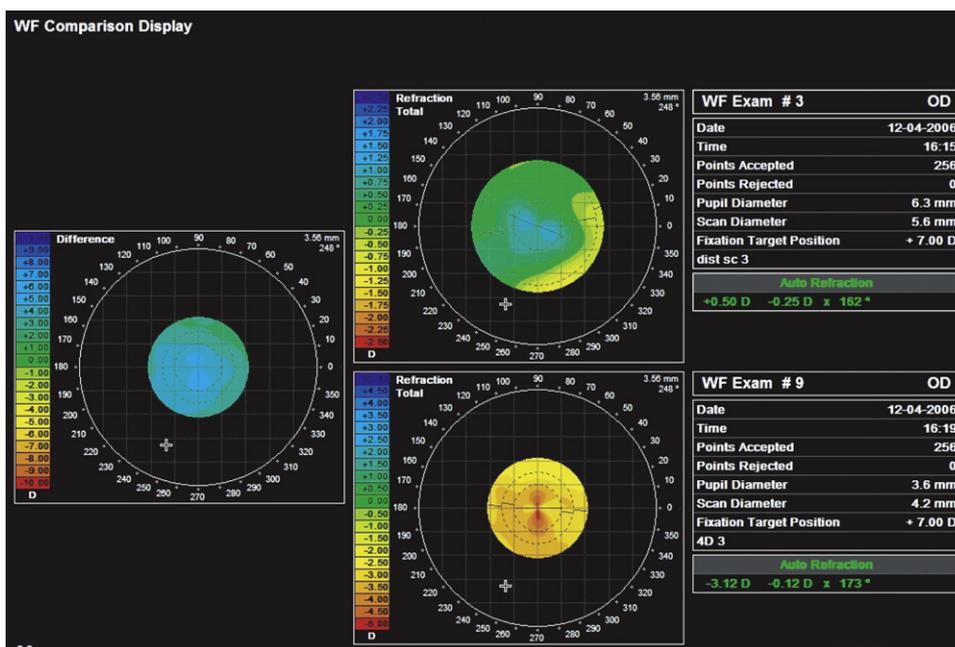


Figure 5. Wavefront aberration contour maps from a 21-year-old subject for the distant 0.0 D stimulus (*top plot*), 4.0 D stimulus (*bottom plot*), and difference wavefront (*left plot*).

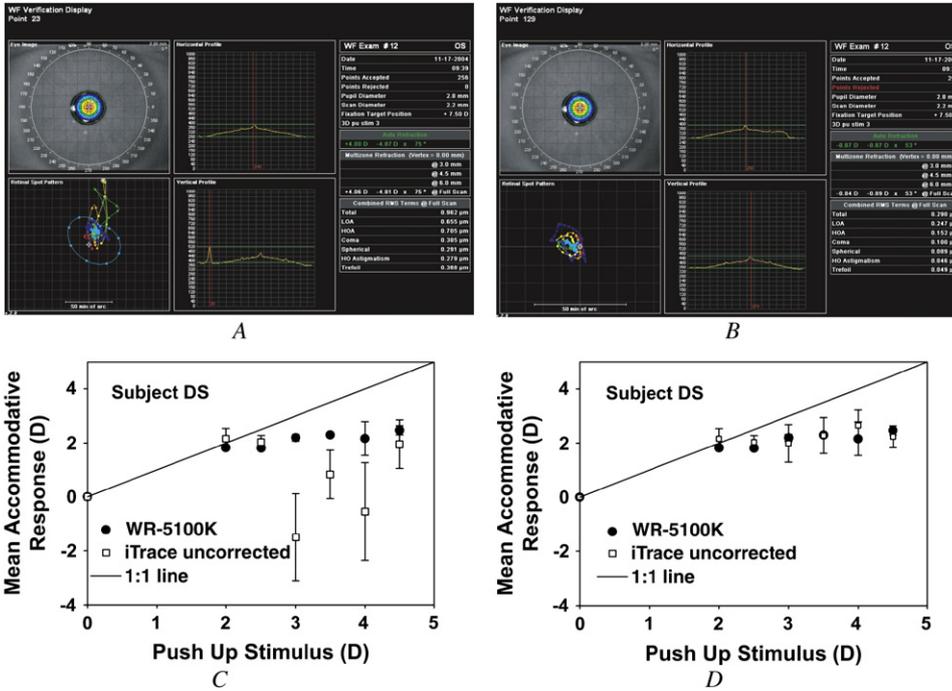


Figure 6. A: Wavefront image from a presbyopic subject (43 years old) showing chaotic retinal spot pattern before aberrant spots were rejected. B: Same subject's wavefront image showing correct concentric rings retinal spot pattern after aberrant spots were rejected. Stimulus response function from the iTrace aberrometer for the same subject before (C) and after (D) aberrant spots were rejected.

measurement is relatively bright and falls on the fovea and can distract the subject from a fixation or accommodation task. The iTrace aberrometer has an open field of view, albeit monocular, which allows real targets to be presented at different distances to provide more compelling accommodative stimuli than internal optical targets. The sequential ray-tracing principle affords a high dynamic range relative to Hartmann-Shack aberrometers for large refractive changes, as might occur in a young eye with high accommodative amplitudes. Despite minor drawbacks, the iTrace aberrometer is an excellent instrument for the objective

accommodation protocols such as the one described here. The additional wavefront aberration data that an aberrometer provides can be extremely valuable for understanding aspects of the optical changes that occur in the eye during accommodation.

Different aberrometers are not necessarily equally good for measuring accommodation. Aberrometers based on the Hartmann-Shack principle have limited dynamic range. A high refractive error can cause adjacent spots from the microarray lens to cross. Because the spots are detected simultaneously in Hartmann-Shack systems (as opposed to sequentially in the iTrace), the crossed spots may not be identified correctly. However, this is unlikely to present a problem in subjects with limited accommodative amplitudes.^{35,36,43} A sequential ray-tracing system enables more beams to pass through small pupils than may be permitted with a fixed Hartmann-Shack microarray lens.³⁶ However, this means that a different sampling density is used in the iTrace ray-tracing system as it will use 256 beams regardless of the pupil size. Therefore, the smaller the pupil, the more dense the sampling distribution for the wavefront measurements.

Previous accommodation testing used minus trial lenses in front of 1 eye to stimulate accommodation, and the response amplitudes were measured in the contralateral eye.⁴⁵ This causes accommodative convergence in the measured eye, and although accommodative amplitude can be measured in this way, this results in an off-axis accommodation measurement.^{7,45} Accommodation can also be stimulated with a trial lens over 1 eye and the response measured in the same

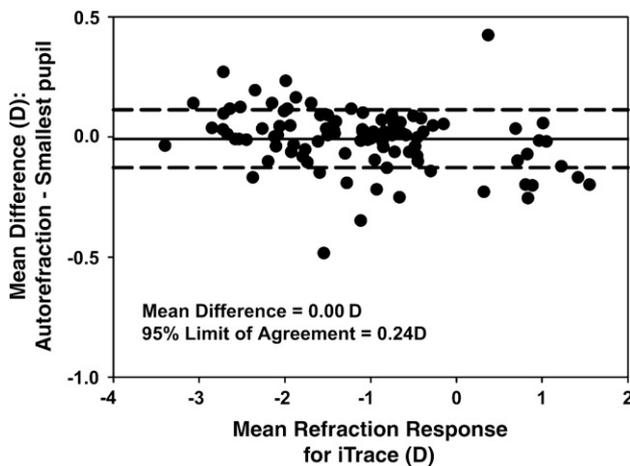


Figure 7. Mean versus difference plot of iTrace aberrometer for refraction measurements of each stimulus distance comparing the spherical refractive error of the autorefraction with the spherical refractive error of the smallest pupil value (3.0 mm).

eye.³² However, attempts to do this with the iTrace aberrometer resulted in errors, presumably due to magnification/minification of the entrance pupil. Stimulating accommodation pharmacologically, such as with topical application of pilocarpine, although especially useful with biometric testing, may not produce an accommodative response of a similar magnitude to a voluntary accommodative effort.⁴⁶ In addition, pilocarpine produces stronger responses in eyes with light colored irides versus dark colored ones.^{7,45} Accommodation can be stimulated and measured objectively in several ways, each with different benefits or drawbacks. A clinical accommodation testing protocol may vary depending on the office setting, time constraints, and instrument availability. An important advantage of the protocol described in the current study is that accommodation was stimulated and measured in the same eye to avoid the issues of off-axis measurements due to consensual convergence response and to provide real targets at real far and near distances to provide the strongest, natural accommodation response.³² However, this can only be achieved with an open field of view instrument or some specialized optical setup that permits the eye to view a real target outside the instrument while the instrument does the on-axis measurement. Although this may be an ideal method, it should not be considered an essential requirement for clinical accommodation measurement. Although the objective measurement is important, it can be achieved in a variety of different protocols with a variety of instruments.

A simple and clearly defined accommodation testing protocol can provide valuable information on the accommodative abilities in any population. By performing systematic testing with at least 3 measurements to determine a mean and standard deviation, one can be confident that measurements are not confounded by subject, examiner, or environmental errors. A dimly illuminated room with controlled and directed lighting (eg, on targets and not on subjects) assists in overcoming subject testing limitations, such as small pupils that allow testing to be performed without dilating eye-drops. Often in clinical testing, only 1 near distance (typically 40 cm) is tested. However, this may not elicit the maximum accommodative effort or it may be too close, thereby preventing the subject from seeing the near target clearly for an adequate accommodative response. This study shows the viability of using the iTrace aberrometer and the WR-5100K autorefractor for clinical objective accommodation measurements. An accommodation testing protocol using either instrument can be accomplished in approximately 15 minutes, providing substantially more information than the subjective push-up test for assessing accommodative ability or than using distance-corrected

near acuity testing of near visual performance as a substitute for accommodation measurement.

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